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A cluster randomised controlled trial of a financial incentive for mothers to improve breastfeeding in areas with low breastfeeding rates: The NOSH study protocol.

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ABSTRACT

Introduction

Breastfeeding can promote positive long-term and short-term health outcomes in both infant and mother. The UK has one of the lowest breastfeeding rates (duration and exclusivity) in the world, resulting in preventable morbidities and associated healthcare costs. Breastfeeding rates are also socially patterned, thereby potentially contributing to health inequalities. Financial incentives have been shown to have a positive effect on health behaviours in previously published studies.

Methods and analysis

Based on data from earlier development and feasibility stages, a cluster (electoral ward) randomised trial with mixed method process and content evaluation was designed. The "Nourishing Start for Health" (NOSH) intervention comprises a financial incentive programme of up to 6 months duration, delivered by frontline healthcare professionals in addition to existing breastfeeding support. The intervention aims to increase the prevalence and duration of breastfeeding in wards with low breastfeeding rates. The comparator is usual care (no offer of NOSH intervention).

Routine data on breastfeeding rates at 6-8 weeks will be collected for 93 clusters (electoral wards) on an estimated 12,498 births. This sample is calculated to provide 80% power in determining a 4% point difference between groups. Content and process evaluation will include interviews with mothers, health care providers, funders and commissioners of Infant Feeding Services. The economic analyses, using a healthcare provider's perspective, will be two-fold, including a within-trial cost-effectiveness analysis and beyond-trial modelling of longer term expectations for cost-effectiveness. Results of economic analyses will be expressed as cost per percentage point change in cluster-level in breastfeeding rates between trial arms. In addition, we will present difference in resource use impacts for a range of acute conditions in babies aged 0-6 months.

Ethics and dissemination:

Participating organisations Research and Governance departments approved the study. Results will be published in peer-reviewed journals and at conference presentations.

Trial registration number: ISRCTN44898617

MAIN ARTICLE

BACKGROUND

Breastfeeding

The World Health Organisation (1) recommends that babies are exclusively breastfed until six months, with breastfeeding continuing for up to two years after solid foods have been introduced. This recommendation is supported by all four UK Departments of Health and is based on evidence regarding the long and short-term benefits of breastfeeding (BF) (2, 3). Despite this policy position, and an increase in numbers of women starting to breastfeed (4), 6-8 week breastfeeding rates in the UK have remained low for several decades in contrast to some other developed countries (e.g. Norway, Sweden) where the majority of women breastfeed for at least two months and many for longer. Because infant feeding is socially patterned with women from low-income groups having the lowest rates, low BF rates also have a serious negative impact on inequalities in health.

Financial incentives for behaviour change

Financial incentives have been shown to be effective in promoting a range of positive health behaviours (5) including adopting a healthy diet (6). Women on unemployment benefit in the Quebec province of Canada have routinely been offered financial incentives ($55 per month)

for BF since the mid1990s (7), but there has been no formal evaluation of this or any other financial incentive scheme for BF.

If financial incentives were found to be acceptable, effective in increasing BF rates and cost-effective, this would have implications for future health policy. For example, Pokhrel and Renfrew et al. (8, 9) estimate that over £17 million could be saved each year in the UK, through reduced hospital admissions and fewer visits to GPs relating to four acute child health conditions if exclusive breastfeeding rates were to increase from 7% to 45% at 4 months and if babies fed breastmilk at discharge from neonatal units increased from 35% to 75%. The conditions examined include: gastrointestinal infection, acute otitis media, lower respiratory tract infection and necrotising enterocolitis. In addition, the cost savings and value of life-time health gains for mothers from associated reductions in breast cancer were estimated to exceed £31million for each annual cohort of women (9). Childhood obesity, sudden infant death, and cognitive outcomes – all conditions with important economic implications - were also found to be adversely affected by not breastfeeding, though given the nature of the available evidence it was not possible to attribute specific cost savings from increased breastfeeding rates in regard to these conditions (9).

Breastfeeding and public health

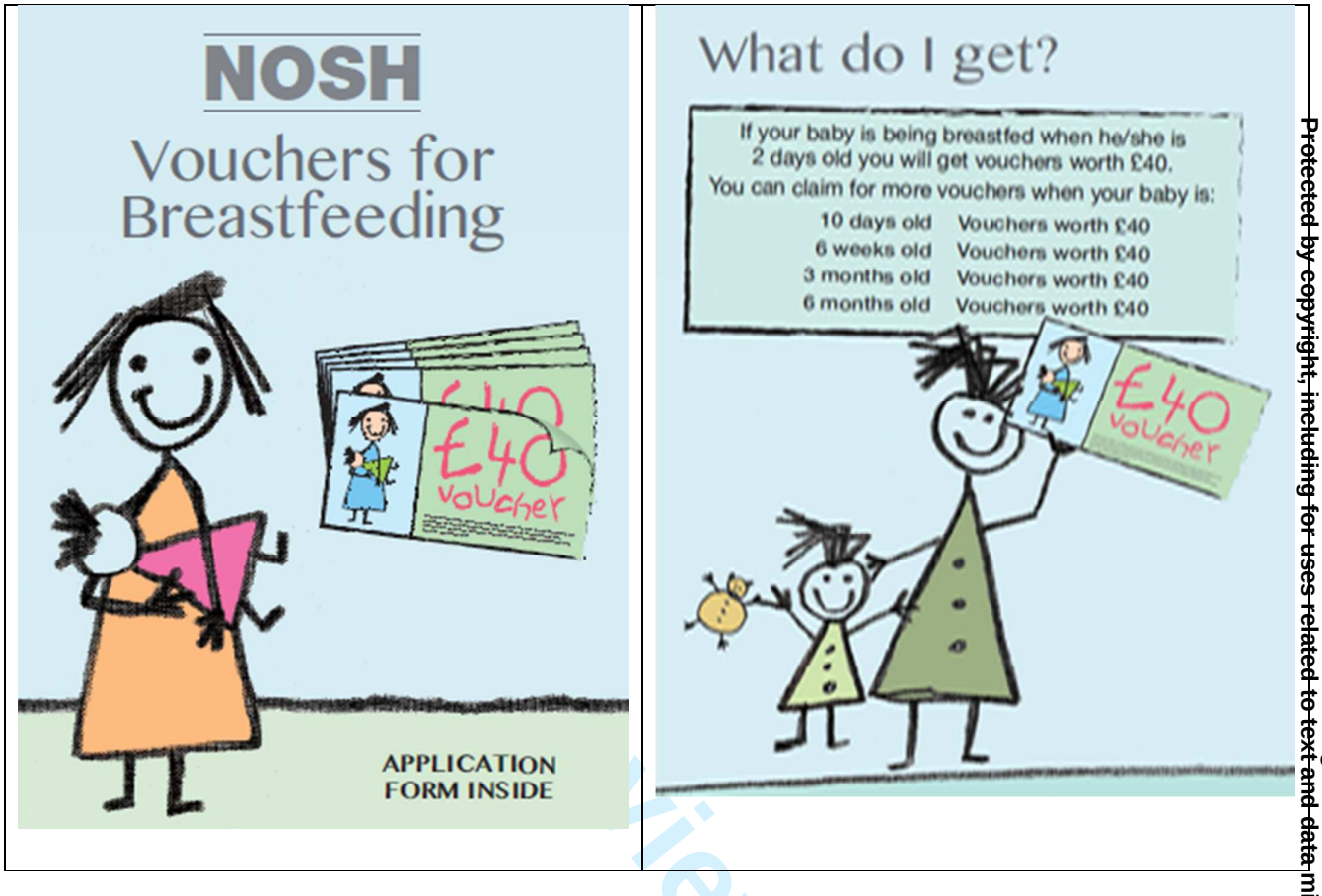
Increasing BF rates is a priority in all four UK countries. In England, BF is a priority White Paper public health policy with the potential to impact on health inequalities, and the 6-8 week BF rate is an outcome in the Public Health Outcomes Framework (10). BF is also a Department of Health “Vital Signs” target (10) and one of 20 key NHS operating plan performance measures. NICE guidance (11) recommends a multi-strategic approach to increase breastfeeding rates. There are therefore strong drivers within the NHS for the identification of successful strategies to improve BF rates. The aim of the trial is to evaluate the effectiveness of a financial incentive scheme (NOSH) designed to increase BF rates in wards with low BF rates.

The intervention

The intervention to be trialled is a behaviour change intervention in the form of the offer of a structured financial incentive (shopping vouchers each worth £40 x 5) to women over a 6-month period – the (Nourishing Start for Health) NOSH Scheme. The intervention will be introduced into the clusters randomised to the Offer Group through the distribution of NOSH Scheme posters and booklets (via Children's Centres, GP surgeries, post offices and other public places in the intervention cluster wards); a press release to the local media, briefing notes and invitations to attend induction sessions about the NOSH scheme to all healthcare providers involved in the provision of infant feeding support services in the intervention clusters. These include: midwives, health visitors, BF support workers and BF peer support workers. Information and materials about the NOSH Scheme are provided to midwifery and health visiting teams working in the trial intervention wards. Midwives and health visitors will discuss the NOSH Scheme with women during routine contact. Taking part in the NOSH Scheme is voluntary; women are able to freely join and leave the NOSH Scheme. To join the NOSH Scheme women complete an application form which must be co-signed by their healthcare provider. On approving the application form, the NOSH Office (based at the University of Sheffield) will forward a 'Welcome Pack'. This contains five NOSH claim forms for vouchers each worth £40 to be signed when the baby is 2 days, 10 days, 6 weeks, 3 months and 6 months) if the baby is still breastfeeding and/ or receiving breastmilk. The 'Welcome Pack' also contains a NOSH fridge magnet, and the NOSH Booklet (Figure 1) detailing information about the scheme and details of local support services in case of problems. Women will sign and date each NOSH Claim Form if her baby is still receiving breast milk and ask their healthcare provider to co-sign the NOSH Claim Form. The NOSH Office will aim to send vouchers to mothers by return post. The intervention will be offered for babies born between 17.2.15 and 17.2.16.

Figure 1

NOSH Booklet



Verification of breastfeeding

The current method used in the UK to collect routine data on infant feeding relies on information exchanged between mother and her healthcare provider. The consensus from the extensive consultation with local stakeholders during an earlier stage of the NOSH Project was that verification of BF should be confirmed by both a signed statement from the mother and a signed statement from their healthcare provider on the Voucher Claim forms. If a healthcare provider has concerns that the baby is not receiving any breast milk, then the healthcare provider can complete and send in a separate “expression of concern form” detailing their concerns. However, it is vital that the NOSH Scheme does not compromise the existing relationship between the mother and the healthcare provider, thus all claims will

be paid regardless of whether or not concerns have been expressed by the healthcare provider. Analysis of the "expression of concern" cards will inform understanding of the reliability of the verification method.

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Study objectives

The primary objective is to test the impact of the offer of the NOSH intervention on 6-8 weeks BF rates in clusters (with low BF rates (<40% breastfeeding at 6-8 weeks).

The secondary objectives are to: (a) test the impact of the intervention on BF rates at initiation in clusters with low BF rates, (b) examine the impact of the intervention on a range of disease outcomes, and impact on health service use in children aged 0-6 months, (c) determine the resource use and costs of providing the intervention by BF initiation, 6-8 weeks and 6 months, (d), examine the cost-effectiveness of the intervention (incremental cost per percentage point change in BF) at 6-8 weeks in wards with low 6-8 week BF rates (<40% at 6-8 weeks), accounting for costs associated with a monetary offer made up to 6 months post birth and costs saved in children aged 0-6 months, and (e), examine the interaction between the effectiveness and cost-effectiveness of the intervention and a range of ward level characteristics, to estimate the incremental cost-effectiveness of intervention over an extended time horizon, using an economic model based analysis.

METHODS, DESIGN AND ANALYSIS

Study design and setting

The trial design is an open pragmatic cluster randomised controlled trial (RCT) with a mixed methods process and context evaluation and an economic evaluation. Clusters (2011 electoral wards) are randomised to either: 1. Offer of a financial incentive scheme to women who live in a designated cluster (intervention arm) or 2. No Offer (control arm).

Districts are defined as the whole (or sometimes part) of a local government council (e.g. Metropolitan Borough Council, City Council or a County Council). In order for a district to be eligible, the district must have:

- electoral wards with low BF rates (< 40% at 6-8 weeks)
- not be currently providing financial incentives to breastfeed
- provide approvals for midwives and health visitors to help deliver the scheme

Sampling frame & recruitment

The sampling frame for the trial is all clusters (electoral wards) with low BF rates (< 40% at 6-8 weeks) in five districts (Sheffield, North Derbyshire, Rotherham, Doncaster and Bassetlaw). Clusters (2011 electoral wards) in each district were screened for eligibility using the most recent data on breastfeeding available when planning the trial. A total of 93 clusters were identified with a total estimated 12,498 births for the trial period in 2015/16.

Inclusion and exclusion criteria

All women aged 16 years and over, ordinarily resident in each ward, and with an estimated date of delivery of before the end of the trial period on 18th February 2016, will be eligible to apply to join the NOSH Scheme. No exclusion criteria are stipulated; exclusion will be determined on a case-by-case basis by healthcare providers using their clinical judgement.

Outcomes

The primary outcome measure is the cluster-level 6-8 week breastfeeding period prevalence over the intervention time period (1st April 2015 to 31st March 2016). Breastfeeding will be defined as any breastfeeding (and will include babies who are receiving supplementary food as well as breastfeeding, and exclusively breastfed babies). The primary outcome will use routine 6-8wk BF data analysed at cluster (electoral ward) level. Secondary outcomes include: BF initiation period prevalence; exclusive BF rate; number and length of admissions

to hospital with: gastrointestinal tract infection, otitis media, respiratory tract infection, necrotising enterocolitis, and any (all) hospital admissions.

Data collection

Data used in this study will come from several sources, measured at a cluster level (defined by postcode) including local routine data from district public health departments and local NHS Trusts on breastfeeding rates, census data and hospital episode statistics with further linkage to health resource groups. We will use routine data to determine cluster-level 6-8 week BF prevalence (these data are based on healthcare provider's professional judgement, after discussion with the mother). Cluster (ward) level descriptive data will be collected using demographic data from the 2011 census, midyear population estimates and deprivation data from the English Index of Deprivation. Cluster level covariates will include deprivation (IMD 2010), mother's age, ethnicity, birth rate (from local routine data sources), 6-8 week BF rate routine data collected from Public Health and Child health Information services. Cluster secondary outcome measures from routine data will include BF initiation and exclusive BF and number and length of hospital admissions.

Risk to accessing primary outcome data

The transfer of the commissioning of the 0-5 Healthy Child Programme from the NHS to local authorities in October 2015 may impact on the trial's access to routine 6-8 week BF data. Although national systems are being set up to ensure good routine data collection for 6-8 week BF prevalence, local organisational challenges may mean that data availability and quality varies by district/ provider.

Sample size

The primary outcome measure is cluster-level 6-8 week breastfeeding period prevalence over the intervention time period. The ICC (0.01) was estimated from the most recently available 6-8 week BF rates in the clusters in the sampling frame. Based on data from 82 clusters and 12,498 births the mean cluster size was 152. The proportion of babies being breastfed at 6-8 weeks was 27.9% (3496/12498).

Assuming a 4% point increase in 6-8wk breastfeeding rates between the intervention and comparator groups represents a clinically/practically important difference; an ICC of 0.01; average cluster size of 152 births and a mean 6-8 week breastfeeding rate of 28% in the control arm then with 5,162 births per group (10,324 in total) the trial is powered to detect a 4% point increase in breastfeeding rates (from 28% to 32%) as statistically significant at the 5% (two-sided) level and 80% power. For a cluster RCT this will require a minimum of 68 clusters to be randomised (152 per group).

Randomisation

The cluster random allocation sequence was generated by the study statistician (SJW), who was not involved in the enrolment of clusters, using computer-generated random numbers, stratified by district, of variable block size. The random allocation sequence was implemented by the CR who assigned the clusters (wards) to the interventions.

There is no blinding of trial participants, care providers, outcome assessors, or data analysts.

Statistical methods

As the trial is a parallel group cluster randomised controlled trial (cRCT), with a usual (control) treatment arm, data will be reported and presented according to the revised CONSORT statement for cluster randomised controlled trials (12) . All statistical exploratory tests will be two-tailed with alpha = 0.05. The analysis will be performed on an intention to treat basis (ITT). The analysis of the outcome data will be carried out at the cluster level,

using aggregate cluster level summary data on breastfeeding rates for each cluster, as we will not have individual specific mother level outcome data.

The primary objective is to evaluate the clinical-effectiveness of the intervention (NOSH Scheme) compared to a usual care control group, in new mothers, on BF rates at 6-8 weeks in clusters with low BF rates (<40% at 6-8 weeks). Aggregate cluster level summary BF rates, at 6-8 weeks will be compared, between the intervention and control groups, using a multiple linear regression model with regression coefficients estimated by weighted ordinary least squares (OLS).

The primary analysis will be a multiple linear regression model with terms for the baseline cluster BF rate, district, randomised group and will be weighted with a weight which is proportional to the inverse of the variance of the estimated BF rate outcome. The effectiveness of the NOSH intervention in the intervention period will be tested by the size and significance of the group term in the multiple linear regression model. A 95% confidence interval (CI) for the group term for breastfeeding at 6-8 weeks between the intervention and control group will be reported, from the model, along with its associated P-value.

A sensitivity analysis will be performed alongside this primary analysis and will include additional baseline cluster level covariates, such as: cluster level deprivation (IMD 2010); cluster level age and ethnicity as defined above; cluster level birth rate; cluster level maternal smoking rate at delivery in the multiple linear regression model. Again a 95% confidence interval (CI) for the group term for breastfeeding at 6-8 weeks between the intervention and control group will be reported, from the model, along with its associated P-value. This estimate will be plotted alongside the primary analysis estimate in a meta-analysis style forest plot graph. Secondary cluster level outcomes (e.g. BF initiation) will be analysed in a similar way with a similar model for the primary outcome. Any missing cluster-level primary outcome (breastfeeding at 6-8 weeks) data will be imputed using a variety of

imputation methods including: Last Observation Carried Forward (LOCF); regression and multiple imputation.

An exploratory sub-group analysis will be performed using multiple linear regression with the primary outcome, summary BF rates at 6-8 weeks, as the response. We will use an interaction statistical test between the randomised intervention group and subgroup to directly examine the strength of evidence for the difference between treatment group (Intervention versus Control) varying between subgroups. District, cluster level age (% women aged 16-44), ethnicity (% non-white) and socioeconomic deprivation will be the only prior defined sub groups to be considered for interaction test. Sub-group analysis will be performed regardless of the statistical significance on the overall intervention effect. The regression coefficients for the interactions between treatment group and each sub group will be presented with the associated confidence intervals and P-values.

Economic evaluation

The base case within-trial cost-effectiveness analysis will compare the NOSH offer made to women over a 6 month period post birth versus no offer made, from a health care provider perspective. It will be tied to the primary outcome at 6-8 weeks and reported as cost per percentage point change in breastfeeding rates at cluster level.

Cost will account for changes in resource use from the intervention and consequences of changes in health service use. Data collection will include a) costs that do not vary by cluster or participant (e.g. time spent setting up and negotiating coverage of the voucher scheme) and need to be apportioned to clusters b) costs that may vary by cluster but not by individual participant (e.g. induction and training of staff): c) costs that vary by participant (e.g. number of vouchers sent, contacts made to NOSH office) that can be grouped by cluster. These data will be sourced using diaries, interviews, administrative records, and the contact logging

system at the NOSH office. Resource use consequences of the offer will reflect the difference in resource use impacts from hospital admissions for a range of acute conditions (GI infections, otitis media, respiratory tract infections, necrotising enterocolitis) in babies aged 0-6 months. Cluster level Hospital Episode Statistics (HES) on in-patient and emergency admissions will be converted into the relevant health resource group code using a reference costs code to group and a unit cost assigned according to the national reference costs (13). Other resource use will be valued using unit costs based on NHS reference costs (13) and other national averages,,e.g. PSSRU 2014 (14), to generate nationally generalisable estimates.

The incremental cost-effectiveness analysis will be based on regression models fitted separately for costs and the primary outcome, accounting for correlation between costs and effects and missing data where appropriate. The unit of analysis, as that of the effectiveness analysis, will be cluster level. The regression based analyses controlling for covariates and cluster effect will be used to estimate changes in breastfeeding, health service use and costs between trial arms.

Deterministic sensitivity and scenario analysis will explore: the impact of using all admissions rather than admissions for the four selected conditions; the potential roll-out of the NOSH scheme; and a sub-group analysis may be included if appropriate. Probabilistic sensitivity analysis will estimate precision of the cost-effectiveness estimates and present cost-effectiveness acceptability curves and compute incremental net benefit (INB) statistics for specific values of decision-makers WTP for %-point change in breastfeeding rates. Beyond-trial modelling of longer term expectations for cost-effectiveness will be undertaken, with methods reported elsewhere.

Intervention process & context evaluation

Process and context evaluation helps researchers to distinguish between results that are due to the intervention succeeding or failing, and those that may be influenced by the social/organisational context or implementation of the intervention. Such evaluations are especially valuable in community-based trials (15, 16). Where a cluster design is used, an additional value resides in the ability of an evaluation to assess the impact of the local context on the implementation of the intervention in each setting (cluster-ward). This is likely to be particularly relevant to trials of public health initiatives as the negative consequences of the environment, resource shortages, organisational change, competing demands and leadership can affect an organisation's ability to effectively deliver an intervention (17, 18). The process/context evaluation will also be used to explore any unintended consequences of the intervention.

Monitoring of the process and delivery of the intervention will be conducted using a mixture of qualitative and quantitative methods. Individual level data will be sought on the views of healthcare providers, commissioners, funders and policy makers regarding the process of delivering the intervention and the completeness and accuracy of the routinely collected 6-8wk BF data using interviews and focus groups. Topic guide refinement, sampling strategies and data collection and analysis will be iterative to address the specific research questions. Awareness of the intervention and views and experiences of the intervention will be collected using interviews and focus groups with mothers and social media.

Qualitative data analysis

NVivo software package will be used to enable complex organisation and retrieval of qualitative data. Framework analysis (19) will be used to analyse the data in order to enhance understanding of social phenomena in order to influence social policy in the UK. Concepts, categories and themes will be identified and coded before comparison with other data to provide analytical categories.

Ethics and Dissemination

NHS Research Ethics Committee approvals and local authority Research Governance permissions have been obtained for healthcare providers in the study five districts to participate.

RESULTS: developing and testing the feasibility of the intervention

This trial forms the third stage of a research project exploring the potential of financial incentives to increase BF in areas with low rates.

The first stage developed the idea, assessed the acceptability of the financial incentive 'shopping vouchers for breastfeeding' scheme in principle, agreed the components of the scheme with local women (20) and midwives, health visitors (21), and obtained permissions from the relevant authorities to test the scheme.

The second stage assessed the feasibility (acceptability and implementation) of the scheme in the real world in three small areas (an electoral ward in North Derbyshire, a "neighbourhood" in Sheffield and a township in Rotherham). The main findings were that midwives and health visitors were willing to alert women to the scheme, and co-sign application forms and voucher claims; and that women joined the NOSH Scheme, claimed vouchers and preferred supermarket and high street vouchers to vouchers for local independent shops.

TRIAL STATUS

Data collection is ongoing

DISCUSSION

The results of this large cluster randomised controlled trial will be used to inform commissioners and other public health decision-makers about the acceptability,

effectiveness and cost-effectiveness of behaviour change support in the form of financial incentives to mothers to breastfeed in areas with low breastfeeding rates. This trial will add to the growing body of knowledge on the role of financial incentives in public health. If the intervention is found to be effective, then this would contribute to future policy discussions on how financial for breastfeeding might be used to improve the long-term health of the population, reduce the risk of disease and obesity in infancy, childhood and adulthood.

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Authors' contributions

CR conceived the intervention and CR, MS, JB, MJR, SW, KJT and JFR designed the initial study. HW, SE, NA, SS helped with the later stages of the study design. CR wrote all drafts of the protocol with significant contributions from all authors at all stages. All authors contributed, read and approved the final manuscript.

The sponsor of the trial is the University of Sheffield (URMS129897) and the contact is k.rooney@sheffield.ac.uk

All information collected will be kept strictly confidential. Any information which would allow individual participants or healthcare professionals to be identified will not be released. The project will comply with all aspects of the Data Protection Act 1998. Participant confidentiality and anonymity will be maintained throughout the duration of the project and in the dissemination of results. Specific consent for how data will be stored, used and destroyed is sought using the participant Information Sheet and Consent Form. Personal details from women applying to participate in the NOSH Scheme will be maintained to allow the NOSH

Office to administer the NOSH SCHEME. These data will include name, address, contact telephone numbers and/or email address, birth date of baby.

All participant data will be stored confidentially and securely in locked filing cabinets or on the Project Drive on University of Sheffield computers (accessible only to relevant project personnel using password protected access) at ScHARR and will only be available to identified NOSH Project staff.

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Competing interests: None of the authors have any competing interests.

Ethics approval: The study protocol has been approved by NHS and local authority Research Governance and Research Ethics Committees. District level consent (NHS and Council) has been obtained from lead organisations of healthcare professionals involved in delivering infant feeding services.

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ABSTRACT

Introduction

Breastfeeding can promote positive long-term and short-term health outcomes in both infant and mother. The UK has one of the lowest breastfeeding rates (duration and exclusivity) in the world, resulting in preventable morbidities and associated healthcare costs. Breastfeeding rates are also socially patterned, thereby potentially contributing to health inequalities. Financial incentives have been shown to have a positive effect on health behaviours in previously published studies.

Methods and analysis

Based on data from earlier development and feasibility stages, a cluster (electoral ward) randomised trial with mixed method process and content evaluation was designed. The "Nourishing Start for Health" (NOSH) intervention comprises a financial incentive programme of up to 6 months duration, delivered by frontline healthcare professionals, in addition to existing breastfeeding support. The intervention aims to increase the prevalence and duration of breastfeeding in wards with low breastfeeding rates. The comparator is usual care (no offer of NOSH intervention).

Routine data on breastfeeding rates at 6-8 weeks will be collected for 92 clusters (electoral wards) on an estimated 10,833 births. This sample is calculated to provide 80% power in determining a 4% point difference in breastfeeding rates between groups. Content and process evaluation will include interviews with mothers, health care providers, funders and commissioners of Infant Feeding Services. The economic analyses, using a healthcare provider's perspective, will be two-fold, including a within-trial cost-effectiveness analysis and beyond-trial modelling of longer term expectations for cost-effectiveness. Results of economic analyses will be expressed as cost per percentage point change in cluster-level in breastfeeding rates between trial arms. In addition, we will present difference in resource use impacts for a range of acute conditions in babies aged 0-6 months.

Ethics and dissemination:

Participating organisations Research and Governance departments approved the study.

Results will be published in peer-reviewed journals and at conference presentations.

Trial registration number: ISRCTN44898617

Protocol Version 3.1 21/05/2015

MAIN ARTICLE

INTRODUCTION

Breastfeeding

The World Health Organisation (1) recommends that babies are exclusively breastfed until six months, with breastfeeding continuing for up to two years after solid foods have been introduced. This recommendation is supported by all four UK Departments of Health and is based on evidence regarding the long and short-term benefits of breastfeeding (BF) (2, 3). Despite this policy position, and an increase in numbers of women starting to breastfeed (4), 6-8 week breastfeeding rates in the UK have remained low for several decades in contrast to some other developed countries (e.g. Norway, Sweden) where the majority of women breastfeed for at least two months and many for longer. Because infant feeding is socially patterned with women from low-income groups having the lowest rates, low BF rates also have a serious negative impact on inequalities in health.

Financial incentives for behaviour change

Financial incentives have been shown to be effective in promoting a range of positive health behaviours (5) including adopting a healthy diet (6). Women on unemployment benefit in the Quebec province of Canada have routinely been offered financial incentives ($55 per month)

for BF since the mid1990s (7), but there has been no formal evaluation of this or any other financial incentive scheme for BF.

If financial incentives were found to be acceptable, effective in increasing BF rates and cost-effective, this would have implications for future health policy. For example, Pokhrel and Renfrew et al. (8, 9) estimate that over £17 million could be saved each year in the UK, through reduced hospital admissions and fewer visits to GPs relating to four acute child health conditions if exclusive breastfeeding rates were to increase from 7% to 45% at 4 months and if babies fed breastmilk at discharge from neonatal units increased from 35% to 75%. The conditions examined include: gastrointestinal infection, acute otitis media, lower respiratory tract infection and necrotising enterocolitis. In addition, the cost savings and value of life-time health gains for mothers from associated reductions in breast cancer were estimated to exceed £31million for each annual cohort of women (9). Childhood obesity, sudden infant death, and cognitive outcomes – all conditions with important economic implications - were also found to be adversely affected by not breastfeeding, though given the nature of the available evidence it was not possible to attribute specific cost savings from increased breastfeeding rates in regard to these conditions (9).

Breastfeeding and public health

Increasing BF rates is a priority in all four UK countries. In England, BF is a priority White Paper public health policy with the potential to impact on health inequalities, and the 6-8 week BF rate is an outcome in the Public Health Outcomes Framework (10). BF is also a Department of Health “Vital Signs” target (10) and one of 20 key NHS operating plan performance measures. NICE guidance (11) recommends a multi-strategic approach to increase breastfeeding rates. There are therefore strong drivers within the NHS for the identification of successful strategies to improve BF rates.

Results of development and feasibility testing stages

This trial forms the third stage of a research project exploring the potential of financial incentives to increase BF in areas with low rates.

The first stage developed the idea, assessed the acceptability of the financial incentive 'shopping vouchers for breastfeeding' scheme in principle, agreed the components of the scheme with local women (12) and midwives, health visitors (13), and obtained permissions from the relevant authorities to test the scheme.

The second stage assessed the feasibility (acceptability and implementation) of the scheme in the real world in three small areas (an electoral ward in North Derbyshire, a "neighbourhood" in Sheffield and a township in Rotherham). The main findings (14) were that midwives and health visitors were willing to alert women to the scheme, and co-sign application forms and voucher claims; and that women joined the NOSH Scheme, claimed vouchers and preferred supermarket and high street vouchers to vouchers for local independent shops.

Aim of the study

The aim of the study is to evaluate the effectiveness of a financial incentive scheme (NOSH) designed to increase BF rates in wards with low BF rates using a cluster (electoral ward) randomised trial with mixed method process and content evaluation.

METHODS, DESIGN AND ANALYSIS

Study objectives

The primary objective is to test the impact of the offer of the NOSH intervention on 6-8 weeks BF rates in clusters (with low BF rates <40% breastfeeding at 6-8 weeks).

The secondary objectives are to: (a) test the impact of the intervention on BF rates at initiation in clusters with low BF rates, (b) examine the impact of the intervention on a range of disease outcomes, and impact on health service use in children aged 0-6 months, (c) determine the resource use and costs of providing the intervention by BF initiation, 6-8

weeks and 6 months, (d), examine the cost-effectiveness of the intervention (incremental cost per percentage point change in BF) at 6-8 weeks in wards with low 6-8 week BF rates (<40% at 6-8 weeks), accounting for costs associated with a monetary offer made up to 6 months post birth and costs saved in children aged 0-6 months, and (e), examine the interaction between the effectiveness and cost-effectiveness of the intervention and a range of ward level characteristics, to estimate the incremental cost-effectiveness of intervention over an extended time horizon, using an economic model based analysis.

Study design and setting

The trial design is an open pragmatic cluster randomised controlled trial (RCT) with a mixed methods process and context evaluation and an economic evaluation. Clusters (2011 electoral wards) are randomised to either: 1. Offer of a financial incentive scheme to women who live in a designated cluster (intervention arm) or 2. No Offer (control arm) (Figure 1 NOSH Trial Schema).

Districts are defined as the whole (or sometimes part) of a local government council (e.g. Metropolitan Borough Council, City Council or a County Council). In order for a district to be eligible, the district must have:

- electoral wards with low BF rates (< 40% at 6-8 weeks)
- not be currently providing financial incentives to breastfeed
- provide approvals for midwives and health visitors to help deliver the scheme

Figure 1 NOSH trial schema

The intervention

The intervention to be trialled is a behaviour change intervention in the form of the offer of a structured financial incentive (shopping vouchers each worth £40 x 5) to women over a 6-month period – the (Nourishing Start for Health) NOSH Scheme. The intervention will be introduced into the clusters randomised to the Offer Group through the distribution of NOSH Scheme posters and booklets (via Children's Centres, GP surgeries, post offices and other public places in the intervention cluster wards); a press release to the local media, briefing notes and invitations to attend induction sessions about the NOSH scheme to all healthcare providers involved in the provision of infant feeding support services in the intervention clusters. These include: midwives, health visitors, BF support workers and BF peer support workers. Information and materials about the NOSH Scheme are provided to midwifery and health visiting teams working in the trial intervention wards. Midwives and health visitors will discuss the NOSH Scheme with women during routine contact. Taking part in the NOSH Scheme is voluntary; women are able to freely join and leave the NOSH Scheme. To join the NOSH Scheme women complete an application form which must be co-signed by their healthcare provider. On approving the application form, the NOSH Office (based at the University of Sheffield) will forward a 'Welcome Pack'. This contains five NOSH claim forms for vouchers each worth £40 to be signed when the baby is 2 days, 10 days, 6 weeks, 3 months and 6 months) if the baby is still breastfeeding and/ or receiving breastmilk. The 'Welcome Pack' also contains a NOSH fridge magnet, and the NOSH Booklet (Figure 2) detailing information about the scheme and details of local support services in case of problems. Women will sign and date each NOSH Claim Form if her baby is still receiving breast milk and ask their healthcare provider to co-sign the NOSH Claim Form. The NOSH Office will aim to send vouchers to mothers by return post. The intervention will be offered for babies born between 17.2.15 and 17.2.16.

Figure 2 NOSH Vouchers for Breastfeeding Booklet

Verification of breastfeeding in order to receive vouchers

The current method used in the UK to collect routine data on infant feeding relies on information exchanged between mother and her healthcare provider. The consensus from the extensive consultation with local stakeholders during an earlier stage of the NOSH Project was that verification of BF should be confirmed by both a signed statement from the mother and a signed statement from their healthcare provider on the Voucher Claim forms. If a healthcare provider has concerns that the baby is not receiving any breast milk, then the healthcare provider can complete and send in a separate "expression of concern form" detailing their concerns. However, it is vital that the NOSH Scheme does not compromise the existing relationship between the mother and the healthcare provider, thus all claims will be paid regardless of whether or not concerns have been expressed by the healthcare provider. Analysis of the "expression of concern" cards will inform understanding of the reliability of the verification method.

Sampling frame & recruitment

The sampling frame for the trial is clusters (electoral wards) with low BF rates (< 40% at 6-8 weeks) in five districts (Sheffield, North Derbyshire, Rotherham, Doncaster and Bassetlaw). Clusters (2011 electoral wards) in each district were screened for eligibility using the most recent data on breastfeeding available, when planning the trial. Following randomisation, a total of 92 clusters (Figure 3) were included in the trial with a total estimated number 10,833 births for the one-year trial period.

Figure 3 RCT Districts, Intervention and Control Clusters (electoral wards)

Inclusion and exclusion criteria for scheme participants

All women aged 16 years and over, ordinarily resident in each ward, and with an estimated date of delivery of between 18th February 2015 and before the end of the trial period on 17th February 2016, will be eligible to apply to join the NOSH Scheme. No exclusion criteria are stipulated; exclusion will be determined on a case-by-case basis by healthcare providers using their clinical judgement.

Randomisation

The cluster random allocation sequence was generated by the study statistician (SJW), who was not involved in the enrolment of clusters, using computer-generated random numbers, stratified by district, of variable block size. The random allocation sequence was implemented by CR who assigned the clusters (wards) to the interventions. There is no blinding of trial participants, care providers, outcome assessors, or data analysts.

Outcomes

The primary outcome measure is the cluster-level 6-8 week breastfeeding period prevalence over the intervention time period (1st April 2015 to 31st March 2016). Breastfeeding will be defined as any breastfeeding (and will include babies who are receiving supplementary food as well as breastfeeding, and exclusively breastfed babies). The primary outcome will use routine 6-8wk BF data analysed at cluster (electoral ward) level. Secondary outcomes include: BF initiation period prevalence; exclusive BF rate; number and length of admissions to hospital with: gastrointestinal tract infection, otitis media, respiratory tract infection, necrotising enterocolitis, and any (all) hospital admissions.

Data collection: Data used in this study will come from several sources, measured at a cluster level (defined by postcode) including local routine data from district public health departments and local NHS Trusts on breastfeeding rates, census data and hospital episode

statistics with further linkage to health resource groups. We will use routine data to determine cluster-level 6-8 week BF prevalence (these data are based on healthcare provider's professional judgement, after discussion with the mother). Cluster (ward) level descriptive data will be collected using demographic data from the 2011 census, midyear population estimates and deprivation data from the English Index of Deprivation. Cluster level covariates will include deprivation (IMD 2010), mother's age, ethnicity, birth rate (from local routine data sources), 6-8 week BF rate routine data collected from Public Health and Child health Information services. Cluster secondary outcome measures from routine data will include BF initiation and exclusive BF and number and length of hospital admissions.

Risk to accessing primary outcome data: The transfer of the commissioning of the 0-5 Healthy Child Programme from the NHS to local authorities in October 2015 may impact on the trial's access to routine 6-8 week BF data. Although national systems are being set up to ensure good routine data collection for 6-8 week BF prevalence, local organisational challenges may mean that data availability and quality varies by district/ provider.

Sample size

The primary outcome measure is cluster-level 6-8 week breastfeeding period prevalence over the intervention time period. The ICC (0.01) was estimated from the most recently available 6-8 week BF rates in the clusters in the sampling frame. Based on data from 92 clusters and an estimated 10,833 births per year the mean cluster size was 118. The proportion of babies being breastfed at 6-8 weeks was estimated as 27.6% (2,985/10,833).

Assuming a 4% point increase in 6-8wk breastfeeding rates between the intervention and comparator groups represents a clinically/practically important difference; an ICC of 0.01; average cluster size of 118 births and a mean 6-8 week breastfeeding rate of 28% in the control arm then with 4,463 births per group (8,926 in total) the trial is powered to detect a 4% point increase in breastfeeding rates (from 28% to 32%) as statistically significant at the 5% (two-sided) level and 80% power. For a cluster RCT this will require a minimum of 76

clusters to be randomised (38 clusters per group).

Data Analysis Plan

Statistical methods

As the trial is a parallel group cluster randomised controlled trial (cRCT), with a usual (control) treatment arm, data will be reported and presented according to the revised CONSORT statement for cluster randomised controlled trials (15). All statistical exploratory tests will be two-tailed with alpha = 0.05. The analysis will be performed on an intention to treat basis (ITT). The analysis of the outcome data will be carried out at the cluster level, using aggregate cluster level summary data on breastfeeding rates for each cluster, as we will not have individual specific mother level outcome data.

The primary objective is to evaluate the clinical-effectiveness of the intervention (NOSH Scheme) compared to a usual care control group, in new mothers, on BF rates at 6-8 weeks in clusters with low BF rates (<40% at 6-8 weeks). Aggregate cluster level summary BF rates, at 6-8 weeks will be compared, between the intervention and control groups, using a multiple linear regression model with regression coefficients estimated by weighted ordinary least squares (OLS).

The primary analysis will be a multiple linear regression model with terms for the baseline cluster BF rate, district, randomised group and will be weighted with a weight which is proportional to the inverse of the variance of the estimated BF rate outcome. The effectiveness of the NOSH intervention in the intervention period will be tested by the size and significance of the group term in the multiple linear regression model. A 95% confidence interval (CI) for the group term for breastfeeding at 6-8 weeks between the intervention and control group will be reported, from the model, along with its associated P-value.

A sensitivity analysis will be performed alongside this primary analysis and will include

additional baseline cluster level covariates, such as: cluster level deprivation (IMD 2010); cluster level age and ethnicity as defined above; cluster level birth rate; cluster level maternal smoking rate at delivery in the multiple linear regression model. Again a 95% confidence interval (CI) for the group term for breastfeeding at 6-8 weeks between the intervention and control group will be reported, from the model, along with its associated P-value. This estimate will be plotted alongside the primary analysis estimate in a meta-analysis style forest plot graph. Secondary cluster level outcomes (e.g. BF initiation) will be analysed in a similar way with a similar model for the primary outcome. Any missing cluster-level primary outcome (breastfeeding at 6-8 weeks) data will be imputed using a variety of imputation methods including: Last Observation Carried Forward (LOCF); regression and multiple imputation.

An exploratory sub-group analysis will be performed using multiple linear regression with the primary outcome, summary BF rates at 6-8 weeks, as the response. We will use an interaction statistical test between the randomised intervention group and subgroup to directly examine the strength of evidence for the difference between treatment group (Intervention versus Control) varying between subgroups. District, cluster level age (% women aged 16-44), ethnicity (% non-white) and socioeconomic deprivation will be the only prior defined sub groups to be considered for interaction test. Sub-group analysis will be performed regardless of the statistical significance on the overall intervention effect. The regression coefficients for the interactions between treatment group and each sub group will be presented with the associated confidence intervals and P-values.

Economic evaluation

The base case within-trial cost-effectiveness analysis will compare the NOSH offer made to women over a 6 month period post birth versus no offer made, from a health care provider perspective. It will be tied to the primary outcome at 6-8 weeks and reported as cost per percentage point change in breastfeeding rates at cluster level.

Cost will account for changes in resource use from the intervention and consequences of changes in health service use. Data collection will include a) costs that do not vary by cluster or participant (e.g. time spent setting up and negotiating coverage of the voucher scheme) and need to be apportioned to clusters b) costs that may vary by cluster but not by individual participant (e.g. induction and training of staff): c) costs that vary by participant (e.g. number of vouchers sent, contacts made to NOSH office) that can be grouped by cluster. These data will be sourced using diaries, interviews, administrative records, and the contact logging system at the NOSH office. Resource use consequences of the offer will reflect the difference in resource use impacts from hospital admissions for a range of acute conditions (GI infections, otitis media, respiratory tract infections, necrotising enterocolitis) in babies aged 0-6 months. Cluster level Hospital Episode Statistics (HES) on in-patient and emergency admissions will be converted into the relevant health resource group code using a reference costs code to group and a unit cost assigned according to the national reference costs (16). Other resource use will be valued using unit costs based on NHS reference costs (16) and other national averages,,e.g. PSSRU 2014 (17), to generate nationally generalisable estimates.

The incremental cost-effectiveness analysis will be based on regression models fitted separately for costs and the primary outcome, accounting for correlation between costs and effects and missing data where appropriate. The unit of analysis, as that of the effectiveness analysis, will be cluster level. The regression based analyses controlling for covariates and cluster effect will be used to estimate changes in breastfeeding, health service use and costs between trial arms.

Deterministic sensitivity and scenario analysis will explore: the impact of using all admissions rather than admissions for the four selected conditions; the potential roll-out of the NOSH scheme; and a sub-group analysis may be included if appropriate. Probabilistic sensitivity

analysis will estimate precision of the cost-effectiveness estimates and present cost-effectiveness acceptability curves and compute incremental net benefit (INB) statistics for specific values of decision-makers WTP for %-point change in breastfeeding rates. Beyond-trial modelling of longer term expectations for cost-effectiveness will be undertaken, with methods reported elsewhere. We will explore the possibility of generating a cost per QALY in the decision-analytic model based analysis.

Intervention process & context evaluation

Process and context evaluation helps researchers to distinguish between results that are due to the intervention succeeding or failing, and those that may be influenced by the social/organisational context or implementation of the intervention. Such evaluations are especially valuable in community-based trials (18, 19). Where a cluster design is used, an additional value resides in the ability of an evaluation to assess the impact of the local context on the implementation of the intervention in each setting (cluster-ward). This is likely to be particularly relevant to trials of public health initiatives as the negative consequences of the environment, resource shortages, organisational change, competing demands and leadership can affect an organisation's ability to effectively deliver an intervention (20, 21). The process/context evaluation will also be used to explore any unintended consequences of the intervention.

Monitoring of the process and delivery of the intervention will be conducted using a mixture of qualitative and quantitative methods. Individual level data will be sought on the views of healthcare providers, commissioners, funders and policy makers regarding the process of delivering the intervention and the completeness and accuracy of the routinely collected 6-8wk BF data using interviews and focus groups. Topic guide refinement, sampling strategies and data collection and analysis will be iterative to address the specific research questions. Awareness of the intervention and views and experiences of the intervention will be collected using interviews and focus groups with mothers and social media.

Qualitative data analysis

NVivo software package will be used to enable complex organisation and retrieval of qualitative data. Framework analysis (22) will be used to analyse the data in order to enhance understanding of social phenomena in order to influence social policy in the UK. Concepts, categories and themes will be identified and coded before comparison with other data to provide analytical categories.

Ethics and Dissemination

NHS Research Ethics Committee approvals and local authority Research Governance permissions have been obtained for healthcare providers in the five trial districts to participate. NHS REC reference: 13/WM/0299

TRIAL STATUS

Data collection is ongoing

DISCUSSION

The results of this large cluster randomised controlled trial will be used to inform commissioners and other public health decision-makers about the acceptability, effectiveness and cost-effectiveness of behaviour change support in the form of financial incentives to mothers to breastfeed in areas with low breastfeeding rates. This trial will add to the growing body of knowledge on the role of financial incentives in public health. If the intervention is found to be effective, then this would contribute to future policy discussions on

how financial for breastfeeding might be used to improve the long-term health of the population, reduce the risk of disease and obesity in infancy, childhood and adulthood.

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Authors' contributions

CR conceived the intervention and CR, MS, JB, MJR, SW, KJT and JFR designed the initial study. HW, SE, NA, SS helped with the later stages of the study design. CR wrote all drafts of the protocol with significant contributions from all authors at all stages. All authors contributed, read and approved the final manuscript.

The sponsor of the trial is the University of Sheffield (URMS129897) and the contact is k.rooney@sheffield.ac.uk

All information collected will be kept strictly confidential. Any information which would allow individual participants or healthcare professionals to be identified will not be released. The project will comply with all aspects of the Data Protection Act 1998. Participant confidentiality and anonymity will be maintained throughout the duration of the project and in the dissemination of results. Specific consent for how data will be stored, used and destroyed is sought using the participant Information Sheet and Consent Form. Personal details from women applying to participate in the NOSH Scheme will be maintained to allow the NOSH Office to administer the NOSH SCHEME. These data will include name, address, contact telephone numbers and/or email address, birth date of baby.

All participant data will be stored confidentially and securely in locked filing cabinets or on the Project Drive on University of Sheffield computers (accessible only to relevant project

personnel using password protected access) at ScHARR and will only be available to identified NOSH Project staff.

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The NOSH Trial Steering Committee provides overall supervision of the trial and monitors trial progress and conducts and advises on scientific credibility. The Trial Steering Committee (TSC) carries the responsibility for deciding whether the trial needs to be stopped. The members are listed in the table below

Name	Position
Dr Andrew Furber	Director of Public Health, Wakefield (Chair)
Professor Andrew Briggs	Professor of Health Economics and Health Technology Assessment, Glasgow University
Professor David Tappin	Professor of Clinical Trials for Children, School of Medicine, University of Glasgow
Dr Clare Relton	Principle Investigator (NOSH), Senior Research Fellow, ScHARR, University of Sheffield
Prof Mary Renfrew	(Co-investigator) Professor of Mother and Infant Health, University of Dundee
Gavin Malloch	MRC Observer
Prof Jon Nicholl	Representative of host institution, Dean of ScHARR, Professor of Health Services Research, University of Sheffield. Director NIHR School for Public Health Research

Dissemination: Results of the trial will be presented to DH and other policy colleagues in a timely and usable form. Professional bodies such as RCM, CPHVA, RCPCH, RCGP, RCOG, RSPH, UKPHA will be proactively contacted and offered access to relevant information. We will also work with the media to publicise the findings of our research. Our

knowledge transfer and exchange plan reflects the needs of different audiences, both academic and non-academic. Academic, professional and service user publications will be prepared on the methods and findings of the different stages of the programme of work. Substantive publications will be targeted at journals and conferences with the most appropriate audiences, and will include versions for professional and service user communities. Papers will report the findings of the different components of the study, and the development of the methods used and methodological challenges. Open access journals will be targeted where possible, Lay audiences will be reached through conferences organised by the NCT and other voluntary groups, and the national NGO Forum. Access to findings will be offered to all research participants, and we will use the same communication networks and agencies that we will be using for data collection to ensure rapid dissemination to all the key professional and voluntary sector networks, and will use local media to support this. We will use our University web sites to disseminate information to academic, professional and user communities and the study has a dedicated website for the public and researchers.

https://www.shef.ac.uk/scharr/sections/ph/research/breastmilk

Competing interests: None of the authors have any competing interests.

Ethics approval: The study protocol has been approved by NHS and local authority Research Governance and Research Ethics Committees. District level consent (NHS and Council) has been obtained from lead organisations of healthcare professionals involved in delivering infant feeding services.

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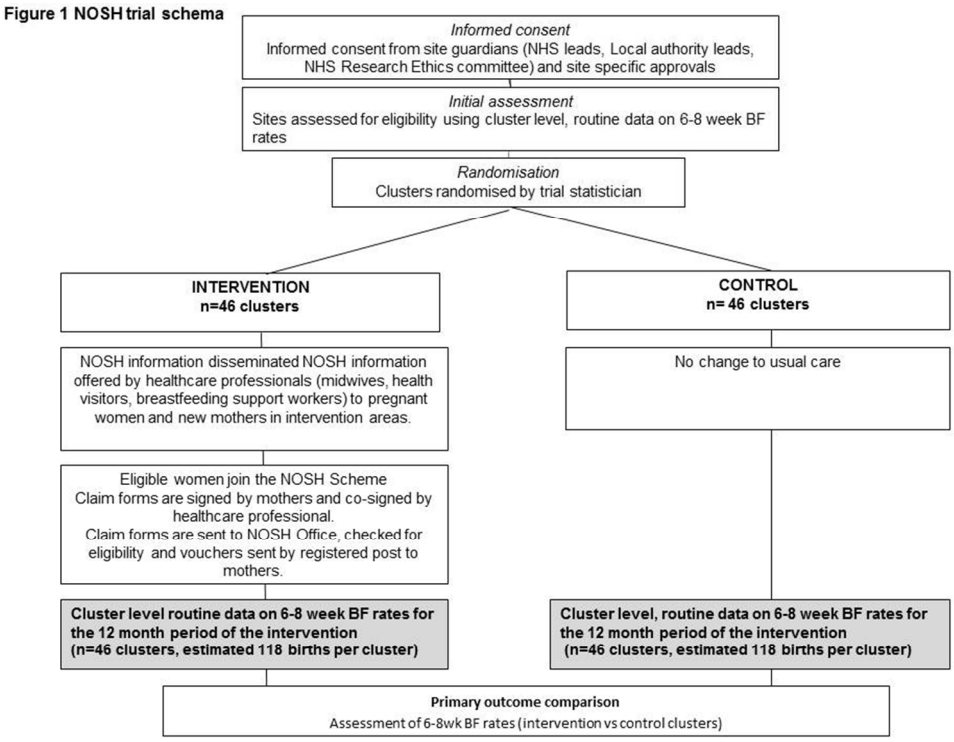

Figure 1 NOSH Trial Schema
81x60mm (300 x 300 DPI)

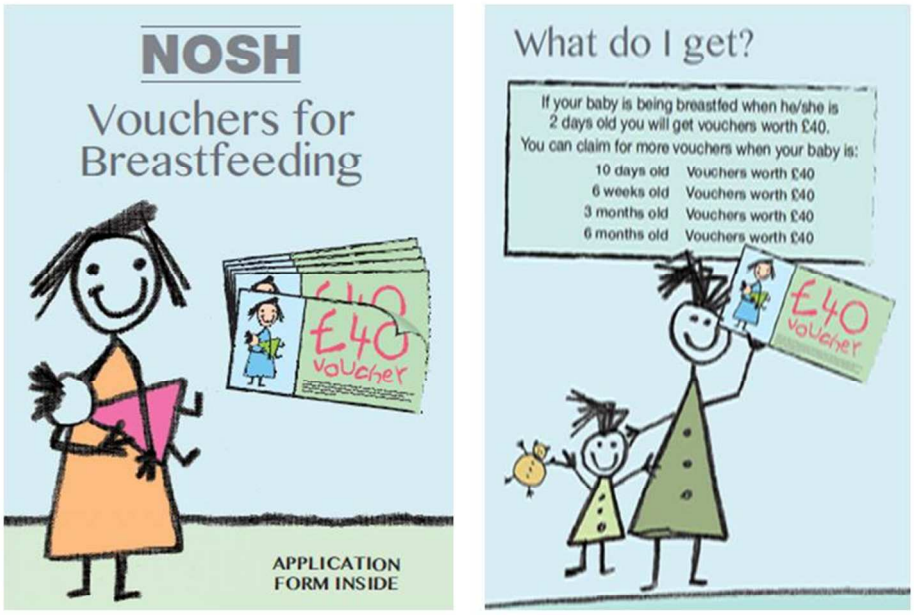

Figure 2 NOSH Vouchers for Breastfeeding Booklet
81x60mm (300 x 300 DPI)

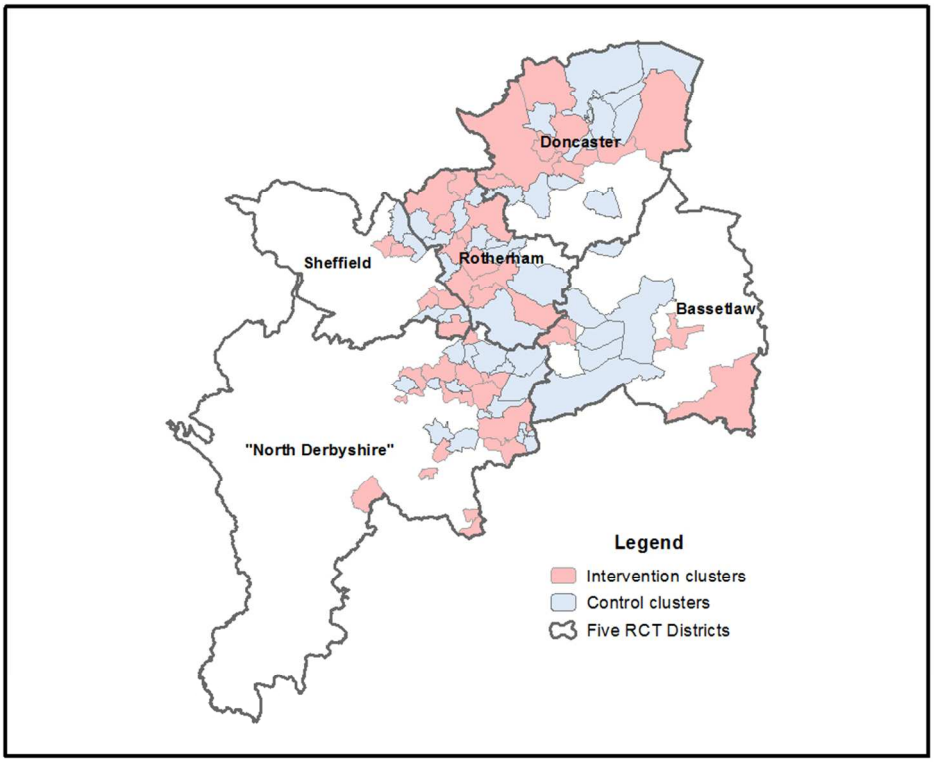

Figure 3 RCT Districts, Intervention and Control Clusters (electoral wards)

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	____1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_____3_____
	2b	All items from the World Health Organization Trial Registration Data Set	____1- 20_____
Protocol version	3	Date and version identifier	_____3_____
Funding	4	Sources and types of financial, material, and other support	_____19_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_____1_____
	5b	Name and contact information for the trial sponsor	_____18_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_____19_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	_____19_____

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3 - 4
	6b	Explanation for choice of comparators	5
Objectives	7	Specific objectives or hypotheses	5-6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	11
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	n/a
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	16
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	11
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	see p.11 and Figure 1 on p.7

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	_____12___
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	n/a as areas (not people) are randomised and analysed.
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	____11_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a (see response to item 15)
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a (see response to item 15)
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a (see response to item 15)
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	_____13__

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a (see response to item 15)
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	_____18_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	____13-17____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	__16-17____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	____n/a_____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Still to be constituted
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	___n/a_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	_____16_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	already obtained see p17

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_____n/a_____
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	already obtained see p17
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	__n/a_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	____18_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	___n/a_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	____n/a_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_____20_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	____none as yet_
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_____n/a___
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____n/a_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Correction: *Cluster randomised controlled trial of a financial incentive for mothers to improve breast feeding in areas with low breastfeeding rates: the NOSH study protocol*

Relton C, Strong M, Renfrew MJ, *et al*. Cluster randomised controlled trial of a financial incentive for mothers to improve breast feeding in areas with low breastfeeding rates: the NOSH study protocol. *BMJ Open* 2016;6:e010158. The first and last names of the penultimate author of this paper are transposed. The author's name is 'Sue Easton'.

BMJ Open 2016;**6**:e010158corr1. doi:10.1136/bmjopen-2015-010158corr1